NHS FIFE POLICY ON INTRODUCTION AND AVAILABILITY OF NEWLY LICENSED MEDICINES

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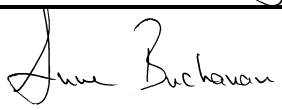
Nurse Director		Last Review Date	

General Note

NHS Fife acknowledges the importance of regular and timely review of policy statements and aims to review policies within the timescales set out.
New policies will be subject to a review date of no more than 1 year from the date of first issue.

Reviewed policies will have a review date set that is relevant to the content (advised by the author) but will be no longer than 3 years.

If a policy is past its review date then the content will remain extant until such time as the policy review is complete and the new version published.

1. FUNCTION

1.1. This policy sets out the framework for the introduction and availability of newly licensed medicines in NHS Fife, including Formulary Medicines, Non-formulary Medicines, and the process for taking account of advice from the Scottish Medicines Consortium (SMC), arrangements for Individual Patient Treatment Requests (IPTRs) and Co-payments for medicines. Unlicensed medicines are not covered in this policy and are covered by the NHS Fife Policy for the Use of Unlicensed Medicines available on the ADTC website.

2. LOCATION

2.1 All areas of NHS Fife where medicines are prescribed, administered, ordered, stored and supplied.

3. RESPONSIBILITY

3.1 It is the responsibility of all clinicians prescribing, administering, ordering, storing or supplying medicines to be aware of and adhere to the processes in NHS Fife for managing:

- Formulary Medicines
- Non-formulary Medicines
- Individual Patient Treatment Requests, including an Appeal Process
- Co-payments for Medicines

3.2 The Medical Director as Chair of the NHS Fife Area Drug & Therapeutics Committee (ADTC) has responsibility for the content, implementation and monitoring of this policy, in collaboration with a range of clinicians (medical, pharmacy, nursing, AHPs).

3.3 The ADTC will develop, implement and monitor systems and processes for application, submission, decision making, recording, informing and monitoring of newly licensed medicines for formulary, non-formulary or IPTRs use. The ADTC will support process for co-payments of medicines by the patient as outlined in CMO (2009) 3. The role and remit of the ADTC is attached in Appendix 1.

4. OPERATIONAL SYSTEM

4.1 FORMULARY MEDICINES

4.1.1 Medicines included in the NHS Fife Joint Formulary are intended to cover the vast majority of patient requirements, providing clinicians with a wide range of quality and cost-effective prescribing options

4.1.2 The formulary can be accessed via the NHS Fife ADTC website www.fifeadtc.scot.nhs.uk.

4.1.3 The arrangements for the Formulary Review Process and Formulary Submissions Process are outlined in Appendix 3.

4.2. NON FORMULARY MEDICINES

4.2.1 Prescribing from the NHS Fife Joint Formulary is consistent with good clinical practice, however, it is recognised that there may be circumstances where a prescriber considers that an individual patient will benefit from a non-formulary medicine. The Formulary process and classifications are defined in Appendix 2.

4.3 SCOTTISH MEDICINES CONSORTIUM ADVICE

4.3.1 Once a new medicine is licensed, the pharmaceutical company is expected to provide evidence about the medicine to the appropriate body to assess its clinical and cost-effective use in the NHS. In Scotland, this is the Scottish Medicines Consortium (SMC), which is a consortium of NHS Board Area Drug & Therapeutics Committees, to avoid duplication for new medicines assessments by individual ADTCs, to avoid geographical inequity in decision

making and to make the best use of expertise available in Scotland. SMC provides advice to Boards on a monthly basis about the status of all newly licensed medicines, all new formulations of existing medicines and new indications for established products. Boards are obliged to take into account SMC advice in its local decision making processes, HDL 26(2007) 12 April 2007. Other local, regional and national advice is also available and the local processes for dealing with this and SMC advice are outlined in Appendix 2.

4.4 INDIVIDUAL PATIENT TREATMENT REQUESTS (IPTRs)

4.4.1 There may be **very** occasional circumstances where a prescriber considers, following review of published evidence that:

- The individual patient's clinical circumstances and potential response to treatment with the medicine are significantly different to the general population of patients for whom NHS policy is not to use the medicine

and

- The individual patient is likely to gain significantly more benefit from the intervention than might normally be expected from patients for whom NHS policy is not to use the medicine. i.e. to that of the group of individuals upon which the SMC/QIS and NHS Fife Joint Formulary advice is based.

4.4.2 An IPTR for a new medicine may be made when:

- SMC or NHS Quality Improvement Scotland (QIS) has issued "Not Recommended" advice for this medicine, including those medicines "Not Recommended" by SMC due to company non-submission

or

- The request relates to the licensed use of the medicine outwith the SMC restriction

or

- Before SMC or QIS have issued an opinion/recommendation.

4.4.3 The IPTR process does not cover Unlicensed or Off Label medicines use.

4.4.4 It is the responsibility of the requesting clinician to demonstrate the reasons why the patient would be expected to respond differently from the general population on which the SMC decision was based by providing a statement regarding the evidence base and the factors relating to the individual case that makes the case exceptional. Only evidence of clinical need will be considered. To demonstrate exceptionality the patient must be both significantly different from the population of interest and more likely to benefit from the medicines than might be expected for other patients with the condition.

4.4.5 It is the responsibility of the requesting clinician, in discussion with the Clinical Director, Directorate General Manager, Management Accountant as appropriate, to ensure the availability of funding for this medicine.

4.4.6 It is the responsibility of the requesting clinician to support the submission with copies of any relevant supporting published clinical evidence/information, and preferably to have carried out a systematic literature review prior to submission.

4.4.7 The process for submission for an IPTR is outlined in Appendix 4.

4.5 CO-PAYMENTS FOR MEDICINES – Combining NHS and Private Care

4.5.1 All local processes for obtaining medicines via the NHS should be fully considered and exhausted before provision of combined NHS and private care is considered. It is essential when considering combining NHS and private care, that the interests of the patient and the wider principles of the NHS are protected.

4.5.2 NHS and private care should be delivered separately and there should be clear separation in legal status, liability and accountability between NHS and private care provision. In all cases the discrete elements of NHS and private care must be understood by all parties

4.5.3 Where the patient wishes to obtain treatment from the independent health sector, the clinician will be expected to follow the guidance on "Arrangements for NHS Patients Receiving Healthcare Services through Private Healthcare Arrangement" CMO (2009) 3. A patient can opt to obtain treatment from the independent health sector at any time, as long as all local processes for obtaining medicines via the NHS have been fully considered and exhausted.

5. RISK MANAGEMENT

5.1 The standardisation of information required when submitting a request for a medicine to be added to the formulary or for a non-formulary medicine and an IPTR , and the appropriate recording of the decision making process and the decision will contribute to the consistency and robustness of decision making, particularly for IPTRs. This also relates to the recording of the discussion and decision of the Appeal Panel.

5.2 Public Partnership Forum engagement in the development and ongoing reviews of this policy ensures clarity, openness and transparency of the process to support the introduction and availability of newly licensed medicines in NHS Fife.

6.0 REFERENCES

NHS Fife ADTC
http://www.fifeadtc.scot.nhs.uk/

Arrangements for NHS Patients receiving Private Healthcare
http://www.sehd.scot.nhs.uk/publications/DC200812Letter.pdf

A Strengthened Role for the Scottish Medicines Consortium
http://www.show.scot.nhs.uk/sehd/mels/hdl2003_60.pdf

Introduction and Availability of Newly Licensed Medicines in the NHS in Scotland CEL17 (2010) 17 May 2010
http://www.sehd.scot.nhs.uk/mels/CEL2010_17.pdf

Scottish Medicines Consortium (SMC) Advice and Single Technology Appraisals (STAS) from the National Institute for Health and Clinical Excellence (NICE) HDL 26(2007) 12 April 2007
http://www.show.scot.nhs.uk/sehd/mels/HDL2007_26.pdf

Arrangements for NHS Patients receiving Healthcare Services through Private Healthcare Arrangements CMO (2009) 3.
http://www.sehd.scot.nhs.uk/cmo/CMO(2009)private.pdf

A Strengthened Role for the Scottish Medicines Consortium
http://www.show.scot.nhs.uk/sehd/mels/hdl2003_60.pdf

Appendix 1

AREA DRUG & THERAPEUTICS COMMITTEE

Role & Remit

Chair
Medical Director, NHS Fife*

Membership
Operational Division Medical Director
Chief Pharmacist Operational Division*
Chief Pharmacist for Primary Care*
Consultant in Pharmaceutical Public Health
Principal Pharmacist – Clinical Effectiveness*
CHP Clinical Leads or prescribing lead (3)
Operational Division Clinical Directors or nominated prescribing leads (5)
Representative of the Director of Finance NHS Fife
Representative of the Director of Nursing NHS Fife Operational Division
Representative of Mental Health Team
Chair of the Antimicrobial Management Team
Chair of Prescribing and Formulary Development Group
Representative of Allied Health Professions
Representative of the Local Medical Committee
Representative of the Area Pharmaceutical Committee
Representative from Pharmacy at Victoria Hospital
* = Executive Group

Meeting Frequency
Full Committee every 2 months
Executive Group on ad hoc basis when necessary

Reporting arrangements
NHS Fife Executive Team (minutes)

Links
NHS Fife Planning and Finance
NHS Clinical Governance Steering Group
NHS Fife Risk Management Group
NHS Fife Medicines Policy Delivery Group.
NHS Fife Formulary Group.

Status
Advisory committee for all prescribing issues including financial forecasting

Remit
1. To develop and review a Fife wide prescribing strategy.
2. To advise the Planning and Finance of the likely trends in prescribing costs. The group will develop mechanisms to
    a. monitoring current prescribing patterns

   b. bench marking medicines costs against other similar healthcare organisations
   c. horizon scanning for likely new drugs or changes in use of existing medicines.
3. To maintain the NHS Fife Formularies including the main drug formulary, the e-Formulary, the Minor Ailments Service Formulary, the wound care formulary and the antibiotic formulary. This function will be delivered through the appropriate sub groups.
4. To monitor compliance of prescribing with the Fife Formularies.
5. To advise NHS Fife Board and its Committees etc as appropriate on all policies and ethical issues relating to medicines use.
6. To receive advice from the Scottish Medicines Consortium, to integrate that into the NHS Fife formulary where appropriate and to consider the implications for NHS Fife.
7. To liaise with stakeholders in the development of prescribing policy e.g. Infection Control, Medical Equipment Management Group and individuals/groups with responsibility for education and professional development.
8. To develop policies and guidance on prescribing and to lead the implementation of these policies in the CHPs and the Operational Division.
9. To ensure that prescribing guidance is reviewed regularly to keep up to date with clinical evidence.
10. To promote seamless care, with respect to medicines for patients transferring between different care settlings in Fife.
11. To disseminate information and advice on prescribing to promote safe, effective and economic use of medicines.

Appendix 2

SCOTTISH MEDICINES CONSORTIUM

1. Role of the Scottish Medicines Consortium

1.1 Advice about the status of all newly licensed medicines, all major new formulations of existing medicines and major new indications for established products (licensed from January 2002) is provided to NHS Fife by the Scottish Medicines Consortium (SMC).

1.2 The advice from SMC will be available as soon as practical after the launch of the medicine involved (normally within 12 weeks of the product / new indication being launched). The SMC advice takes in to account the clinical and cost effectiveness of the medicine and the decisions are classified into:

- Recommended for use in NHS Scotland
- Recommended for restricted use in NHS Scotland - the terms of the restriction may apply to specified patient groups and specified prescribers
- Not recommended for use in NHS Scotland

1.3 In accordance with NHS HDL (2003) 60 the SMC will specifically advise NHS Boards when a particular medicine must be implemented within 3 months as part of an agreed national programme.

1.4 Where such a national programme is not described, then implementation is a matter for local decision making and planning.

2. Local Process Following Receipt of SMC advice

2.1 The local process within NHS Fife, subsequent to advice from the SMC, is the responsibility of the NHS Fife Area Drugs and Therapeutics Committee (ADTC).

2.2 Where a medicine is not recommended for use in NHS Scotland by the SMC this will be noted by the ADTC, will not be added to the Joint Formulary and no further action will be taken.

2.3 Where a medicine is approved for use in NHS Scotland by the SMC, the Clinical Effectiveness Pharmacist (CEP) for NHS Fife will liaise with local specialists / opinion leaders from both the primary and secondary care setting to gain local opinion on the recommendations made by the SMC. The CEP will provide a summary of local opinion with a recommendation to the ADTC on the status of the new formulation / indication in the NHS Fife Joint Formulary.

2.4 The ADTC will consider the SMC advice and local opinion and will make decisions regarding the inclusion/exclusion of the new medicine/indication within the NHS Fife Joint Formulary.

2.5 For each new medicine, the ADTC will take into account, where appropriate, the following criteria:

- local service delivery implications;
- actions required to enable effective and efficient introduction of the medicine within NHS Fife, including if a local guideline requires to be developed
- potential place in therapy of the new medicine/indication in relation to existing medicines in the formulary
- the cost-effectiveness of the medicine on its own and compared to alternatives already in use, having regard also to the overall medicines budget.

2.6 The possible decisions regarding the introduction of new medicines in NHS Fife are:

- The medicine is included within the Joint Formulary on an unrestricted basis.
- The medicine is excluded from the Joint Formulary but may be prescribed to individual patients on a restricted basis e.g. in line with SMC advice, a local or regional protocol.
- The medicine is excluded from the formulary and classified as Not Preferred.

2.7 The local decision regarding formulary status in NHS Fife will normally be made within 8 weeks of the SMC decision being in the public domain. Information on all decisions made will be communicated to clinicians via the ADTC Minutes and the bi-monthly ADTC Bulletin.

2.8 The SMC Look Forward Annual Report is considered locally to highlight new products and indications that may have a significant impact clinically or financially in Fife.

2.9 It is important to note that the remit of SMC, and thus the ADTC, excludes the assessment of vaccines, branded generics, non-prescription-only medicines, blood products, plasma substitutes and diagnostic drugs. The review of device-containing medicines will be confined to those licensed as medicines by the MHRA/EMA.

3. Local Process Following Receipt of Other National/Regional advice

3.1 In addition to SMC advice the ADTC will consider and comment on NHS QIS validated NICE Multiple Technology Appraisals (MTAs) and highlight where the new recommendations supersede advice previously issued by the SMC.

3.2 The South of Scotland Cancer Network (SCAN) will provide advice on a regional basis to the NHS Lothian Formulary Committee on the managed entry of new cancer medicines, with the exception of medicines used in Haematology where the local decision making process is followed. Guidance issued by SCAN will be discussed and approved at the Lothian Formulary Committee on a regional basis. This information will then be shared with NHS Fife ADTC.

3.3 Recommendations from regional/tertiary care centres for the use of medicines prior to their submission to SMC will be managed through the regional/tertiary care centre IPTR process

3.4 The NHS Fife process for the Managed Entry of New Medicines, New Licensed Indications is shown in Appendix 7.

4. Patient Access Schemes

4.1 Patient Access Schemes(PAS) are proposed by a pharmaceutical company to improve the cost effectiveness of a drug and may facilitate access to medicines in NHS Scotland that are not, or might not in the first instance, found to be cost effective by SMC. PAS can either be finance based, where the NHS receives a rebate or free stock based on usage, or performance based, where the rebate or supply of stock is based on patient response to treatment.

4.2 Pharmaceutical companies submitting a new drug to SMC have to option to submit a PAS at the same time. The national Patient Access Scheme Assessment Group will consider the PAS and make a recommendation. If the PAS is not accepted then the company may resubmit a revised PAS. If the PAS is recommended, the SMC will consider the new drug application along with the PAS. Thus, a PAS will only relate to a new medicine that has been recommended by SMC.

4.3 The ADTC will consider SMC recommendations, which may include a PAS for some specific medicines, as outlined in 2.4 above. If a medicine with a PAS is accepted for use in NHS Fife by the ADTC, then the local process for implementing and managing PASs will be followed.

Appendix 3

FORMULARY MEDICINES

Formulary Review Process

1.1.1 The NHS Fife Joint Formulary is split up into Chapter Sections in line with the structure of the BNF. Each section is updated as part of a rolling programme of reviews approximately every 3 years. A formulary section can be reviewed and updated sooner if required following significant clinical changes in practice e.g. safety alerts, new guidelines.

1.1.2 The review process is led by the Clinical Effectiveness Pharmacist (CEP) with input from local specialists representing Clinicians, Pharmacists and where appropriate Nursing staff and Allied Health Professionals (AHPs). Declarations of interest are requested and noted from all members of the Review Group.

1.1.3 The review takes into account any changes to the Section relating to –
New drugs; new formulations; new indications; new safety information; Scottish Medicines Consortium(SMC) advice, NICE Multiple Technology Assessments(MTAs), NHS QIS advice; new clinical guidance from SIGN, NICE and other recognised national guideline groups; local prescribing trends, cost-effectiveness and the need for economy in the use of public funds.

1.2 Formulary Submissions Process

1.2.1 A Consultant, GP, Senior Pharmacist or Senior Nurse can submit requests to the NHS Fife Area Drug & Therapeutics Committee(ADTC) to add medicines to the NHS Fife Joint Formulary by completing the relevant Formulary Submission Form which can be accessed via the ADTC website www.fifeadtc.scot.nhs.uk. The request must contain adequate supporting information on why the medicine is to be added to the Joint Formulary including a declaration of interest from the applicant.

1.2.2 The ADTC will only consider a request for a medicine that has been accepted for use by the SMC but not previously added to the NHS Fife Joint Formulary.

1.2.3 The ADTC will review the submission, taking into account local opinions. The decision will be communicated to the requesting clinician by the CEP.

1.3 Formulary Classifications

1.3.1 Medicines are categorised in the Formulary using this following classification system:

- **1st / 2nd line Choices** – Products that are recommended within Fife and should normally be used in the majority of patients.

- **Restricted Use** – Products that have been approved by the SMC for a limited indication or for a niche group of patients. These products would not normally be added to the Fife Formulary and should not be prescribed routinely.

However, it would be appropriate for them to be prescribed for patient groups that have been approved by the SMC.

- A list of products / indications falling into the restricted use category will be available on the ADTC website.

- These medicines will be listed in the Fife Formulary as a prescribing note.

- **Not Preferred** – Products that have been assessed by the SMC and been approved for use within NHS Scotland. However, after consultation with local opinion leaders it is decided that there are suitable alternatives that are preferred locally. These products should only be used when Formulary products have been ineffective, not tolerated or are contra-indicated.

- **Not Recommended** – Products that have been assessed by the SMC and have not been approved for use within NHS Scotland. These products should not normally be prescribed within NHS Fife. If SMC approved products are considered inappropriate then a request should be submitted to the ADTC, using the appropriate submission form, requesting the use of the product in an individual patient. (Copies of the form can be downloaded from the ADTC website under Fife Formulary). Evidence to support the submission must be provided.

Appendix 4

INDIVIDUAL PATIENT TREATMENT REQUESTS (IPTRs)

1. An IPTR form will be submitted by the Clinician to the NHS Fife Area Drug & Therapeutics Committee (ADTC) for discussion and decision. This may need to be conducted electronically outwith the formal meeting schedule depending on time constraints. Where there is a clinical urgency, an interim response will be provided within 1-2 working days. Where there is no clinical urgency a response will be provided within 2-3 weeks. Any decisions taken in this way will be ratified at the next scheduled ADTC meeting. The financial impact of the prescribing request will be included within the submission, with an indication of the source of funding and where the costs will be allocated. Where an IPTR submission is not supported by the ADTC the requesting clinician will be advised of the IPTR Appeal process.

2. The Clinician making the submission is most likely to be the Hospital Consultant with overall clinical responsibility for the patient, but may also be the patients' GP or a Non-medical Prescriber.

3. The IPTR request must be considered at a minimum by:

    - NHS Fife Medical Director
    - Director of Pharmacy
    - Specialist Clinician(s) – local or from another Health Board

    Each member must nominate a Deputy to allow decision making to continue if any members of the Panel are unavailable.

4. All members of the panel must declare any interests which could have an impact on impartiality and decision making and this be recorded as part of the record of the consideration of the submission.

5. To support decision making, the ADTC may seek further information and advice from appropriate specialists e.g. MCN leads. All members of the ADTC complete an annual Declaration of Interests which should be available as part of the decision making process.

6. The evidence that the IPTR decision making process will consider may include:

    - SMC/QIS advice and the detailed documentation, where available
    - Information as to why SMC have issued a "Not Recommended" recommendation
    - further information from systematic literature review, where appropriate
    - patient-specific case report from the requesting clinician including the rationale for the IPTR, including treatment history, specific characteristics, prognosis, information on expected response and benefit, consequences of

using/not using the medicine to the patient, consequences of using the treatment including cost, treatment duration and stopping rules.
- Clinician experience with proposed treatment
- Information on how the clinician will demonstrate the response to treatment
- Finance/budget impact applications and support for expenditure from budget holder
- Declarations of interest, where appropriate

7. In making a decision the group will consider:
   - Are the reasons why the patient would be expected to respond differently from the general population on which the SMC decision was based circumstances demonstrated?
   - If the reasons why the patient would be expected to respond differently from the general population on which the SMC decision was based demonstrated, should the request be supported and funded?

8. Written final confirmation of the ADTC decision will be provided to the requesting clinician within 10 working days of the next ADTC. A verbal response may be provided sooner depending on the clinical situation of the patient and the urgency of the request. Any verbal response will be followed up with written confirmation. The requesting clinician is responsible for communicating the outcome of the request to the patient.

9. Where an IPTR request is not supported by the ADTC the requesting clinician will be advised of the Appeal Process.

10. Information will be provided to patients, families, carers and their representatives describing the IPTR process and the Appeal Process. Where clinically appropriate, the patient may be given the opportunity to participate in the IPTR process or by submitting a written statement, with the Clinician providing support.

10. Appeal process

10.1 Where ADTC, having considered all of the available information has decided that a medicine should not be made available for an individual patient, then that patient has the right to appeal that decision.

10.2 Where the patient feels they have grounds for appeal, it is open to them to pursue this. Additionally, where the patient is not satisfied with the way the IPTR was handled, this could include progressing their concerns via the NHS complaints process. Complaints and Appeals can be progressed simultaneously and will not impact on each other.

10.3 An Appeal should be submitted by the Clinician within 14 days of receipt of the decision.

10.4 The Appeal should be lodged in writing to NHS Fife Chief Executive. The Appeal should specify the grounds for appeal together with any supporting documentation.

10.5 An Appeal Panel will be convened with the core membership from NHS Fife:

- Chief Executive
- Board Non-Executive member
- Director of Public Health
- Medical Director or associate Medical Director of equivalent from another Health Board

- Advice and support may be requested from the Director of Pharmacy from another Health Board if required

10.6 All members of the panel must declare any interests which could have an impact on impartiality and decision making and this be recorded as part of the record of the consideration of the submission.

10.7 Appeals can only be lodged on the grounds that due process has not been followed or that the decision making process has in some way been flawed. Where new evidence for the medicine or the patient emerges, this is not considered an appeal but a resubmission should be made through the normal IPTR process. The Appeal panel is expected to consider the following:

- Board policy on IPTRs
- The written evidence submitted in respect of the IPTR
- The written account of the rationale for the IPTR decision reached

10.8 Written confirmation of the Appeal Panel decision will be provided to the Clinician within 10 working days. A verbal response may be provided sooner depending on the clinical situation of the patient and the urgency of the request. The verbal response will be followed up with written confirmation. The Clinician is responsible for communicating the outcome of the appeal to the patient.

10.9 The NHS Fife process for the IPTR process is shown in Appendix 6.

11. Co-payments

11.1 Where the patient wishes to obtain treatment from the independent health sector, the clinician will be expected to follow the guidance on “Arrangements for NHS Patients Receiving Healthcare Services through Private Healthcare Arrangement” CMO (2009) 3. A patient can opt to obtain treatment from the independent health sector at any time, as long as all local processes for obtaining medicines via the NHS have been fully considered and exhausted.

Appendix 5

GOOD PRACTICE FRAMEWORK FOR PATIENT ENGAGEMENT IN IPTRs

1. The following information should be available to patients and the public relating to IPTRs:

    - What constitutes an IPTR in the context of local medicines management and decision making.
    - How, when and by whom an IPTR can be initiated.
    - Information on who can initiate a request.
    - Details of the local contact point to provide advice on IPTRs.
    - Membership of the decision making panel considering an IPTR.
    - What information or evidence will be considered by the decision making panel considering an IPTR and who can submit such information or evidence.
    - The principles or factors that are considered by a decision making panel considering an IPTR.
    - The timescales of decision making for IPTRs .
    - Clear timescales and methods for communicating decisions to patients for whom an IPTR has been made.
    - Information about the grounds on which an appeal can be made, how such appeals can be made, where local advice on appeals can be sought and information about the process of decision making, timescales and communication of outcomes.
    - The information is sensitive to the communications and language needs of patient, families and carers

2. Patient Involvement in the Decision Making Process

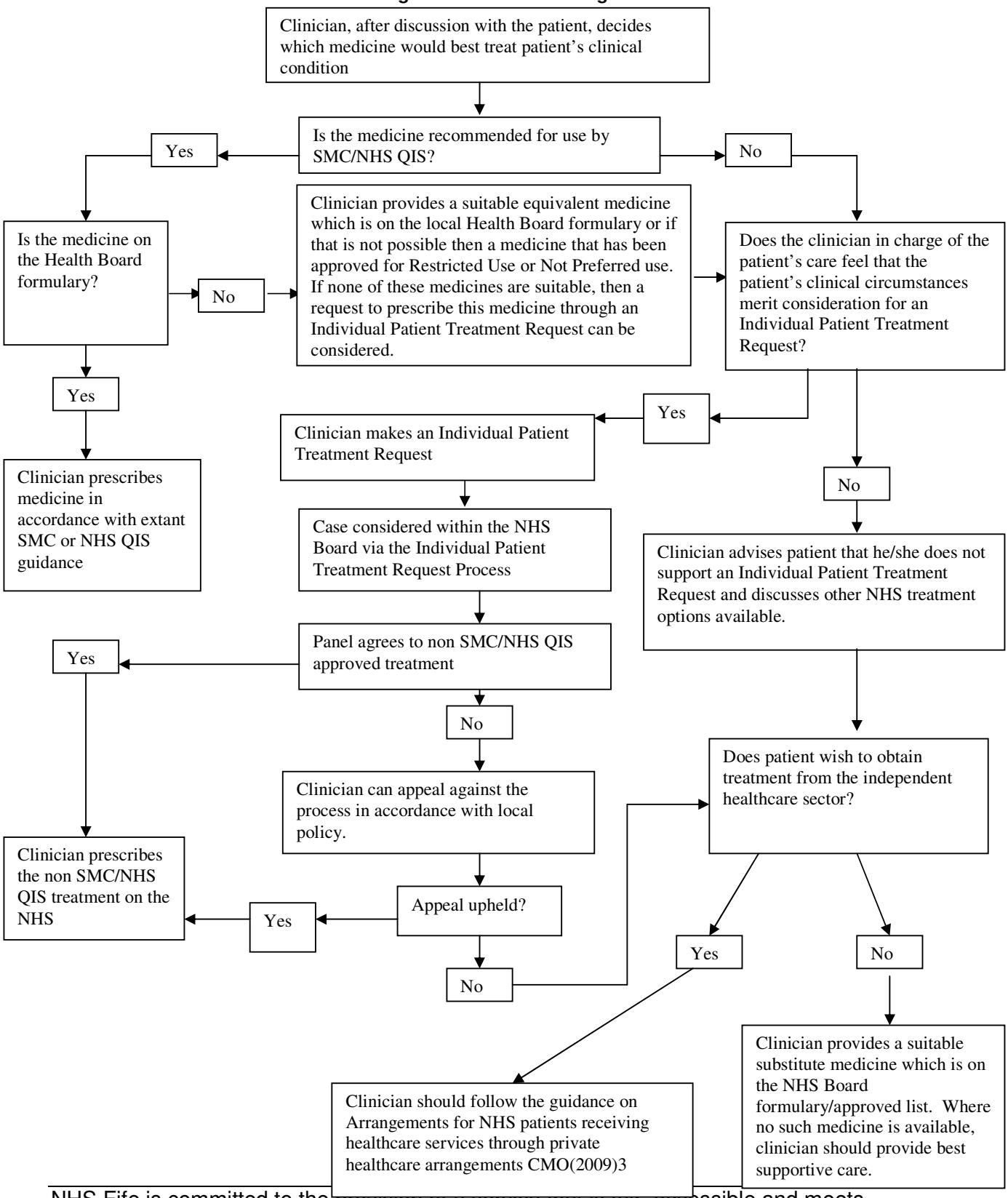
2.1 CEL 19(2010) states that that “where it is clinically appropriate, patients or a patient advocate will be given the opportunity to participate in the process. However, the arrangements will be expected to ensure the application can be

considered on the basis of free and open discussion by the clinicians involved and not breach any patient confidentiality requirements". Therefore,

- Patients will be given the opportunity to participate in the process but there is no requirement on the patient to attend the IPTR decision making meeting or for the Board to provide the opportunity for the patient to attend the meeting.
- Patient involvement should initially be through discussion with the submitting clinician, who will present the case.
- Patients should be given the opportunity to make a statement supporting the IPTR submission made on their behalf in writing, or other appropriate method e.g. voice/video recording where appropriate. The IPTR point of contact will be able to support the patient to provide a statement if they wish.
- The absence of a patient statement will not have a detrimental effect on the IPTR decision making process.
- In situations where a patient is unable to make a statement, a statement will be accepted from an appropriate advocate, where appropriate.
- Where clinically appropriate, patients should be offered the opportunity to have copies of the IPTR documentation that will be available to the decision making panel considering the request. This offer will be made via the agreed point of contact.
- The patient will be informed of the decision by the requesting clinician by an agreed method of communication e.g. telephone call, letter, e-mail etc.
- Where a request is declined, the patient will be able to receive information on the Appeal Process from the agreed point of contact but the Appeal process will only review matters relating to the IPTR process and, therefore, the patient will not participate in the Appeal process beyond the provision of supporting evidence.

Appendix 6

NHS Fife Arrangements for Prescribing Medicines



Equality and Diversity

Equality Rapid Impact Assessment

1) Date: 28th March 2011 **28th March 2011**
2) Title of policy, procedure, strategy etc **NHS Fife Policy On Introduction and Availability of Newly Licensed Medicines**
3) Is this a new policy etc? **Yes**
4) Is this an existing policy etc under review? **No**
5) Please list any existing documents which have been used to inform this Equality Rapid Impact Assessment. CEL17(2010 – Managed Introduction of Newly Licensed Medicines SGHD/CMO(2011)3 "Implementing CEL17(2010): Introduction and Availability of Newly Licensed Medicines in the NHS in Scotland – Good Practice Guidance for NHS Board Management of Individual Patient Treatment Requests(IPTRs)"
6) What is the description of the policy, procedure or strategy? This policy sets out the framework for the introduction and availability of newly licensed medicines in NHS Fife, including Formulary Medicines, Non-formulary Medicines, and the process for taking account of advice from the Scottish Medicines Consortium (SMC), arrangements for Individual Patient Treatment Requests (IPTRs) and Co-payments for medicines.
7) What is the intended outcome of this policy, procedure or strategy? See above
8) Name the individuals or groups who are responsible for undertaking Equality and Diversity Impact Assessment? Director of Pharmacy

9) Which of the protected characteristics will be positively or negatively affected by this policy, procedure or strategy?

	Positively	Negatively	No Impact	Not Known
Ethnic communities including Gypsies Travellers	**+ve**	☐	☐	☐
Gender including transgendered people	**+ve**	☐	☐	☐

Religion and faith and no faith	**+ve**	☐	☐	☐
People with a disability	**+ve**	☐	☐	☐
Age	**+ve**	☐	☐	☐
Sexual Orientation	**+ve**	☐	☐	☐
Socio-economic status including homelessness	**+ve**	☐	☐	☐
Other please state	☐	☐	☐	☐

Equality Rapid Impact Assessment Checklist

10) List any positive impacts that have been identified Yes
11) List any adverse impacts that been identified No
12) Outline any actions proposed to overcome adverse impacts N/A
13) What recommendations have been made to eliminate or reduce adverse impacts? N/A
14) What consultation and involvement has been undertaken to ensure that you have engaged with the local population? **PFP Groups from the CHPs and the Operational Division have commented and comments have been included**
15) Is there a need for more evidence to be collected? No
16) How will NHS Fife undertake the necessary monitoring to ensure that where recommendations have been made that these are implemented? **Core data in relation to outcomes from IPTRs will be collated and reviewed through Area Drug & Therapeutics Committee**

Area that the policy, procedure, strategy or service redesign covers

NHS Fife wide	**Yes**
Dunfermline and West Fife CHP	
Glenrothes and North East Fife CHP	
Kirkcaldy and Levenmouth CHP	
Corporate Directorate	
Operational Division	

Type of policy, procedure, strategy or service redesign

Human Resource policy	
Clinical policy	**Yes**
General policy	
NHS Fife strategy	
Service redesign	
Change papers	
Guidelines and protocols	
Local proceedures	
Financial decisions	
Other	

Contact Information

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